Paper No. 29

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte DAVID E. EDGREN, HOWARD A. CARPENTER,
GURDISH K. BHATTI AND ATUL D. AYER

_____

Appeal No. 1997-1160
Application No. 08/036,566

_____

ON BRIEF

_____

Before, WINTERS, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 24-27. We note that claim 23 was canceled in appellants' after final amendment[1], therefore the examiner's final rejection of claim 23 is not at issue in this appeal.

[1] Paper No. 15, received March 9, 1995.

Claim 24 is illustrative of the subject matter on appeal and is reproduced below:

> 24. A dosage form for administering an anti-Parkinson drug to a patient, wherein the dosage form comprises:
>
> (a) a composition comprising 0.10 mg to 750 mg of an anti-Parkinson drug and a pharmaceutically acceptable carrier for the anti-Parkinson drug selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethyl-cellulose and polyvinylpyrrolidone, which composition in the presence of fluid that contacts the dosage form provides a dispensable anti-Parkinson therapeutic formulation; and wherein the dosage form:
>
> (b) provides the anti-Parkinson drug substantially-free of adverse effects for administration in a rate-controlled metered dose per unit time over 24 hours.

Claim 26 is directed to a method of management of paralysis agitans by administering a drug composition that essentially parallels claim 24. Claims 25 and 27 depend from claims 24 and 26 respectively and add the limitation of a particular anti-Parkinson drug selected from a Markush grouping which includes, inter alia, levodopa, carbidopa, levodopa-carbidopa and trihexyphenidyl.

The reference relied upon by the examiner is:

Physicians' Desk Reference (PDR), 43rd Edition, pp. 1110-111, 1390-391 (1989)

GROUND OF REJECTION

Claims 24-27[2] are rejected under 35 U.S.C. § 103 as being unpatentable over the PDR.

We reverse.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer[3] for the examiner's reasoning in support of the rejection. We further reference appellants' Brief.[4]

THE REJECTION UNDER 35 U.S.C. § 103:

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The PDR teaches dosage forms of the anti-Parkinson drugs trihexyphenidyl (ARTANE®), and Carbidopa-Levodopa (SINEMET®), at concentrations within the claimed range, for the treatment of paralysis agitans. The PDR does not teach applicants' excipients, specifically hydroxypropyl-cellulose, hydroxypropylmethylcellulose or polyvinylpyrrolidone.

[2] We note the following typographical error (Answer, page 2). The examiner refers to claims 23-27 in the rejection under 35 U.S.C. § 103. However, as noted by appellants (Brief, page 2), claim 23 was canceled in the after final amendment received March 9, 1995 (Paper No. 15). The examiner's Advisory Action (Paper No. 16, mailed March 2, 1995) indicated that this amendment would be entered upon the filing of an appeal and that the rejection of claim 23 was now moot. Therefore, the statement of the rejection should refer only to claims 24-27 (the only claims currently pending).
[3] Paper No. 28, mailed September 10, 1996.
[4] Paper No. 25, received April 1, 1996.

The examiner reasons (Answer, page 3) that "one of ordinary skill in the art of the management of paralysis agitans would recognize that the management is effected with the anti-Parkinson agent, regardless of the excipients utilized." Appellants' argue (see e.g., Brief, pages 4 and 6) that the claimed dosage form, which uses a carrier selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethyl-cellulose and polyvinylpyrrolidone provides rate-controlled dosage which is distinct from the prior art. In response the examiner argues (Answer, page 5) that "the formulation for Artane [sic] disclosed in the PDR is as rate-controlled as that of the instant claimed invention."

We remind the examiner that "[t]he Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis." In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). To establish a prima facie case of obviousness, there must be some reason, suggestion, or motivation found in the prior art whereby a person of ordinary skill in the field of the invention would make the substitutions required. That knowledge cannot come from the applicants' disclosure of the invention itself. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 678-79, 7 USPQ2d 1315, 1318 (Fed. Cir. 1988);
In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985).

On the record before us, in contrast to the examiner's position, we find no reasonable suggestion for using any one of appellants' claimed carriers. Under these

circumstances, we are constrained to reach the conclusion that the examiner has failed to provide the evidence necessary to support a prima facie case of obviousness. Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Accordingly, the rejection of claims 24-27 under 35 U.S.C. § 103 is reversed.

REVERSED

Sherman D. Winters	)
Administrative Patent Judge	)
	) BOARD OF PATENT
Donald E. Adams	)
Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
Demetra J. Mills	)
Administrative Patent Judge	)

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